

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)
FREDERICK G. ST. GOAR, *et al.*) Examiner: Unassigned
Application No.: Unassigned) Art Unit: Unassigned
Filed: Herewith)
For: METHOD FOR DELIVERING)
A FLUID TO THE CORONARY)
OSTIA (As Amended))

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Prior to examination, please amend the subject application as indicated below

IN THE TITLE:

Please delete the title and insert the following title instead:

--METHOD FOR DELIVERING A FLUID TO THE CORONARY OSTIA--

IN THE SPECIFICATION:

Please replace the paragraph beginning on page 1, line 5 with the following corrected paragraph:

-- This application is a continuation of U.S. Patent Application No. 09/151,582, filed September 11, 1998, which is a division of Application No. 08/615,152, filed March 12, 1996, now issued as U.S. Patent No. 5,807,318, which is a divisional of Application No. 08/351,850, filed December 7, 1994, now issued as U.S. Patent No. 5,695,457. The complete disclosures of the aforementioned related U.S. patent applications are hereby incorporated herein by reference for all purposes.--

IN THE CLAIMS:

Claims 1, 4-6, 9, 11 and 17 have been amended. Please replace the set of claims currently on file with the following set of claims.

1. (Amended) A method of delivering a fluid to a heart of a patient, the heart having a coronary vasculature, comprising the steps of:

- a) introducing at least one distal end of at least one perfusion catheter into a peripheral artery of said patient;
- b) advancing said distal end of said perfusion catheter from said peripheral artery into at least one coronary ostium communicating with said coronary vasculature of said patient;
- c) occluding said coronary ostium with an occlusion device proximate said distal end of said perfusion catheter;
- d) delivering a fluid to the heart through the perfusion catheter.

2. The method of claim 1, wherein step d) comprises the substep of infusing a cardioplegic agent through a lumen of said perfusion catheter into said coronary vasculature downstream of said occlusion device.

3. (Amended) The method of claim 1 wherein said fluid is infused through said lumen of said perfusion catheter at a rate of at least approximately 100 ml/min at a pump pressure not exceeding 350 mmHg.

4. (Amended) The method of claim 1, wherein step d) comprises the substep of infusing a mixture of oxygenated blood and a cardioplegic agent to create the fluid and then delivering the fluid through a lumen of said perfusion catheter into said coronary vasculature downstream of said occlusion device at a rate of at least approximately 100 ml/min at a pump pressure not exceeding 350 mmHg.

5. (Amended) The method of claim 1, further comprising the step of:

- e) isolating said coronary vasculature from systemic circulation of said patient by continuing to occlude said coronary ostium with said occlusion device for a period of time after delivering the fluid.

6. (Amended) The method of claim 1, further comprising the step of:
f) maintaining systemic circulation of said patient with peripheral cardiopulmonary bypass.

7. The method of claim 6, wherein step f) comprises:
positioning an arterial cannula in a peripheral artery of said patient;
positioning a venous cannula in a peripheral vein of said patient;
withdrawing venous blood from said patient through a blood flow lumen in said venous cannula;
infusing oxygenated blood into said patient through an infusion lumen in said arterial cannula.

8. The method of claim 1, further comprising the steps of:
g) introducing a third distal end of a catheter through an aortic valve of said heart of said patient;
h) venting a left ventricle of said heart by withdrawing fluid through a venting lumen communicating with said third distal end of said catheter.

9. (Amended) The method of claim 1, wherein step a) comprises introducing a single perfusion catheter having at least two distal ends into said peripheral artery of said patient; step b) comprises advancing said at least two distal ends into at least two coronary ostia; step c) comprises occluding each of said at least two coronary ostia with an occlusion device proximate each of said at least two distal ends, respectively; and step d) comprises delivering the fluid through at least one lumen communicating with said at least two distal ends of said perfusion catheter into said coronary vasculature downstream of said occlusion devices.

10. The method of claim 9, further comprising the steps of:

- g) introducing a third distal end of said perfusion catheter through an aortic valve of said heart of said patient;
- h) venting a left ventricle of said heart by withdrawing fluid through a venting lumen communicating with said third distal end of said catheter.

11. (Amended) The method of claim 1, wherein step a) comprises introducing the distal ends of at least two perfusion catheters into said peripheral artery of said patient; step b) comprises advancing said distal ends of said at least two perfusion catheters into at least two coronary ostia; step c) comprises occluding each of said at least two coronary ostia with an occlusion device proximate each of said distal ends of said at least two perfusion catheters, respectively; and step d) comprises delivering the fluid through at least two lumina communicating with said distal ends of said at least two perfusion catheters, respectively, into said coronary vasculature downstream of said at least two occlusion devices.

12. The method of claim 11, further comprising the steps of:
- g) introducing a distal end of a venting catheter through an aortic valve of said heart of said patient;
 - h) venting a left ventricle of said heart by withdrawing fluid through a venting lumen communicating with said distal end of said venting catheter.

13. The method of claim 1, wherein step c) comprises inflating an inflatable occlusion device to occlude said coronary ostium.

14. The method of claim 1, wherein step a) comprises the substeps of:
introducing a guide catheter having at least one internal lumen into said peripheral artery of said patient; and
introducing said at least one distal end of said at least one perfusion catheter through said at least one internal lumen of said guide catheter.

15. The method of claim 11, wherein step a) comprises the substeps of:
introducing a guide catheter having at least one internal lumen into said peripheral artery of said patient; and
introducing the distal ends of said at least two perfusion catheters through said at least one internal lumen of said guide catheter.

16. The method of claim 11, wherein step a) comprises the substeps of:
introducing a guide catheter having at least two internal lumina into said peripheral artery of said patient; and
introducing the distal end of a first perfusion catheter through a first internal lumen in said guide catheter, and introducing the distal end of a second perfusion catheter through a second internal lumen in said guide catheter.

17. (Amended) The method of claim 1, further comprising the step of:
i) performing coronary artery bypass graft surgery on the heart of the patient.

18. A catheter system for inducing cardioplegic arrest in a heart of a patient, said catheter system comprising:

an elongated catheter shaft, said catheter shaft having at least two distal branches, including:

a first distal branch having a first distal end and a first occlusion device proximate said first distal end, said first distal branch having a first perfusion lumen which communicates with a first distal perfusion port distal to said first occlusion device, and

a second distal branch having a second distal end and a second occlusion device proximate said second distal end, said second distal branch having a second perfusion lumen which communicates with a second distal perfusion port distal to said second occlusion device.

19. A catheter system for inducing cardioplegic arrest in a heart of a patient, said catheter system comprising:

a first perfusion catheter having a first elongated catheter shaft, said first catheter shaft having a first distal end and a first occlusion device proximate said first distal end, said first catheter shaft having a first perfusion lumen which communicates with a first distal perfusion port distal to said first occlusion device, and

a second perfusion catheter having a second elongated catheter shaft, said second catheter shaft having a second distal end and a second occlusion device proximate said second distal end, said second catheter shaft having a second perfusion lumen which communicates with a second distal perfusion port distal to said second occlusion device.

REMARKS

Claims 1-19 are pending in this application.

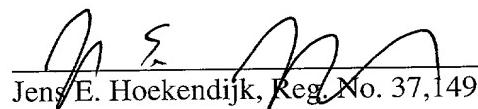
Attached is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned with "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

If a telephone interview would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 412-3322.

Please charge any required fees, including any necessary extension-of-time fees, or credit any overpayment to Deposit Account No. 08-1510.

Respectfully submitted,

Date May 22, 2001



Jens E. Hoekendijk, Reg. No. 37,149

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE TITLE:

**[CARDIOPLEGIA CATHETER SYSTEM]
METHOD FOR DELIVERING A FLUID TO THE CORONARY OSTIA**

IN THE SPECIFICATION:

The paragraph beginning on page 1, line 5 has been amended as follows:

[This application is a divisional of co-pending application Serial No. 08/351,850 filed December 7, 1994, now issued as U.S. Patent No. 5,695,457. The complete disclosures of all of these related applications are incorporated herein by reference for all purposes.]

This application is a continuation of U.S. Patent Application No. 09/151,582, filed September 11, 1998, which is a division of Application No. 08/615,152, filed March 12, 1996, now issued as U.S. Patent No. 5,807,318, which is a divisional of Application No. 08/351,850, filed December 7, 1994, now issued as U.S. Patent No. 5,695,457. The complete disclosures of the forementioned related U.S. patent applications are hereby incorporated herein by reference for all purposes.

IN THE CLAIMS:

1. (Amended) A method of inducing cardioplegic arrest in delivering a fluid to a heart of a patient, the heart having a coronary vasculature, comprising the steps of:
 - a) introducing at least one distal end of at least one perfusion catheter into a peripheral artery of said patient;
 - b) advancing said distal end of said perfusion catheter from said peripheral artery into at least one coronary ostium communicating with said coronary vasculature of said patient;
 - c) occluding said coronary ostium with an occlusion device proximate said distal end of said perfusion catheter;
 - d) [arresting] delivering a fluid to the heart through the perfusion catheter.

3. (Amended) The method of claim [2] 1 wherein said **[cardioplegic agent]** fluid is infused through said lumen of said perfusion catheter at a rate of at least approximately 100 ml/min at a pump pressure not exceeding 350 mmHg.

4. (Amended) The method of claim 1, wherein step d) comprises the substep of infusing a mixture of oxygenated blood and a cardioplegic agent to create the fluid and then delivering the fluid through a lumen of said perfusion catheter into said coronary vasculature downstream of said occlusion device at a rate of at least approximately 100 ml/min at a pump pressure not exceeding 350 mmHg.

5. (Amended) The method of claim 1, further comprising the step of:
e) isolating said coronary vasculature from systemic circulation of said patient by continuing to occlude said coronary ostium with said occlusion device**[while the heart is arrested]** for a period of time after delivering the fluid.

6. (Amended) The method of claim [5] 1, further comprising the step of:
f) maintaining systemic circulation of said patient with peripheral cardiopulmonary bypass.

9. (Amended) The method of claim 1, wherein step a) comprises introducing a single perfusion catheter having at least two distal ends into said peripheral artery of said patient; step b) comprises advancing said at least two distal ends into at least two coronary ostia; step c) comprises occluding each of said at least two coronary ostia with an occlusion device proximate each of said at least two distal ends, respectively; and step d) comprises **[infusing a cardioplegic agent]** delivering the fluid through at least one lumen communicating with said at least two distal ends of said perfusion catheter into said coronary vasculature downstream of said occlusion devices.

11. (Amended) The method of claim 1, wherein step a) comprises introducing the distal ends of at least two perfusion catheters into said peripheral artery of said patient; step b) comprises advancing said distal ends of said at least two perfusion catheters into at least two coronary ostia; step c) comprises occluding each of said at least two coronary ostia with an

occlusion device proximate each of said distal ends of said at least two perfusion catheters, respectively; and step d) comprises [**infusing a cardioplegic agent**] delivering the fluid through at least two lumina communicating with said distal ends of said at least two perfusion catheters, respectively, into said coronary vasculature downstream of said at least two occlusion devices.

17. (Amended) The method of claim 1, further comprising the step of:
 - i) performing coronary artery bypass graft surgery on the [**arrested**] heart of the patient.